JUN 17 2014

6/16/14

PREMARKET NOTIFICATION
510(k) SUMMARY OF SAFETY AND EFFECTIVENESS FOR VANISHPOINT® BLOOD COLLECTION SET
(21 CFR 807.92)

Applicant Name:	Retractable Technologies, Inc. 511 Lobo Lane Little Elm, TX 75068
Phone:	972-294-1010
Contact Person:	Rhonda Wells Regulatory Affairs Manager
Date of Summary Preparation:	June 16, 2014
Trade Name:	EasyPoint™ Needle
Common Name:	Needle, Hypodermic, Single Lumen
Regulation Number:	880.5570
Product Code	FMI: Hypodermic Single Lumen Needle
Device Classification:	Class II

Legally Marketed Substantially Equivalent Device:

K021475 – BD Single Lumen Needle (PrecisionGlide™)
K970803 – VanishPoint® Syringe

Description of Device:

The EasyPoint™ Needle is intended for general purpose percutaneous injection or aspiration of fluids and venipuncture to obtain blood collection.
The device contains a sharps injury prevention feature (needlestick prevention feature-chamber) that covers the entire needle after use. Initially available in sizes of 23G and 25G x 1" and 25G x 5/8" for use with 3mL syringes or smaller.

Intended Use:

The Easy Point™ Needle is intended for use with syringes for general purpose fluid injection and/or aspiration, and venipuncture to obtain blood collection.

The EasyPoint™ Needle aids in the prevention of needlestick injuries.

Engineering Testing:

Performance testing on the EasyPoint™ Needle was performed according to applicable design requirements of ISO 594-1, ISO 594-2, ISO 7864, ISO 7886 and ISO 9626. Those tests include, liquid leakage, air leakage, dead space and needle puncture force. Additional performance tests were developed by Retractable Technologies, Inc. to measure the functionality force, deactivation force, chamber strength/ rigidity, cannula/ hub bond strength.

Simulated Use Study:

A simulated use pre-market study was performed to demonstrate through human factors validation testing that the EasyPoint™ Needle

device performs safely and effectively when used by a variety of healthcare workers in a simulated use scenario.

Comparison of Technical Characteristics:

The subject EasyPoint™ Needle utilizes a retraction based safety mechanism like the predicate device VanishPoint® Syringe. The 2nd predicate device, BD PrecisionGlide® single lumen needle is available as a stand-alone needle but does not have an integrated safety mechanism. The BD single lumen needle is also available as a needle/barrel combination syringe. The EasyPoint™ Needle will initially be sold as a stand-alone needle for use with luer fitting devices. The VanishPoint® Syringe and BD single lumen needle are commercially available in various needle length and gauge sizes. Biocompatibility testing has been performed on the EasyPoint™ Needle in accordance with ISO 10993 with acceptable results.

Substantial Equivalence:

The operation, similar design and materials between the subject device and the predicate devices do not raise new issues of safety and effectiveness when used as labeled. The intended use of the subject and predicate devices is virtually identical. In engineering testing, the subject device performed as well or better than the predicate devices. The Simulated Use Study demonstrates that the subject device will perform as intended. The necessary Biocompatibility testing was performed with acceptable results and a Sterilization Validation was performed according to ISO 11137 to ensure sterility of ($SAL\ 10^{-6}$). It is our opinion that the devices are substantially equivalent.

Conclusion:

The EasyPoint™ Needle is substantially equivalent to the VanishPoint® Syringe and BD PrecisionGlide® single lumen needle. The intended uses are the same No new concerns regarding safety and effectiveness were raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 17, 2014

Retractable Technologies, Incorporated
Ms. Rhonda Wells
Regulatory Affairs Manager
511 Lobo Lane
Little Elm, TX 75068

Re: K133635
Trade/Device Name: EasyPoint™ Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Needle, Hypodermic, Single Lumen
Regulatory Class: II
Product Code: FMI
Dated: March 18, 2014
Received: March 19, 2014

Dear Ms. Wells:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner
-S FDA

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K133635

Device Name

Easy Point Needle

Indications for Use *(Describe)*

The Easy Point Needle is intended for use with syringes for general purpose fluid injections and/or aspiration, and venipuncture to obtain blood collection.

The Easy Point Needle aids the prevention of needlestick injuries.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

FDA

Digitally signed by Richard C. Chapman -S
Date: 2014.06.16 09:35:17 -04'00'

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